

Appl. No. : 10/770,712
Filed : February 3, 2004

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REMARKS

Claims 1 and 20 have been amended. Claims 21-23 have been canceled. Accordingly, Claims 1-20 and 24-30 remain presented for examination. Support for the claim amendments may be found in original claims 22 and 23, and throughout the specification. Thus, no new matter has been added. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Rejections under 35 U.S.C. 112, first paragraph

The Examiner rejected claims 1-30 based on recitation of determination of etiology of an autistic spectrum disorder in a patient. The Examiner alleges that the data presented in the specification does not support determination of etiology. The Examiner acknowledges that the data provided in the specification indicate a correlation between autistic syndrome and an increased level of certain autoantibodies. The Examiner also states that data presented in the specification may support diagnosis of autistic patients. Although Applicants do not agree with the position taken by the Examiner regarding lack of support for determination of the etiology of an autistic spectrum disorder, claims 1 and 20 have been amended to recite methods of diagnosing an autistic spectrum disorder in a patient.

The Examiner also contends that the determination of a combination of at least 3 categories of antigen/antibodies as recited in claim 1 would cause confusion since such determination may produce misleading results because the real causative factor would not be known. Applicant respectfully submits that claim 1 does not recite determination of a particular causative factor. Instead, the claim correlates elevated levels of at least three different antigens/antibodies, at least one of which is infectious agent derived, one of which is toxic chemical derived and one of which is dietary protein-derived. This claim is fully enabled by the specification in Tables 1, 4, 5 and in Example 1 in which the presence of elevated levels of multiple antigens/antibodies as recited in claim 1 were associated with the presence of autism.

In view of the claim amendments and comments presented above, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph (written description).

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Rejection under 35 U.S.C. 102(b)

Claims 20-21 and 24-30 were rejected under 35 U.S.C. 102(b) as being anticipated by Vojdani et al. (*J. Neuroimmunology* 129:168-177, 2002). Claim 20 as amended recites a Markush group containing antibodies to self-tissues or peptides that were recited in canceled claims 22 and 23, which were not rejected as being anticipated by this reference. In order for a claim to be anticipated by a reference, each claim element must be found within the reference. Because these antibodies are neither taught nor suggested by Vojdani et al. (2002), the claims cannot be anticipated.

In view of the claim amendments and comments presented above, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Rejections Under 35 U.S.C. §102(a)

Claims 1-8 and 10-30 were rejected under 35 U.S.C. §102(a) as being anticipated by Vojdani et al. (*Int. J. Immunopathol. Pharmacol.* 16:189-199, 2003). This reference was published less than one year before the filing date of the present application and describes Applicant's own invention. Enclosed herewith is a Declaration under *In re Katz* which states that the other authors listed on the Vojdani et al. reference did not make inventive contributions to the claimed subject matter, thus rendering this rejection moot.

Claims 1-9, 11-15, 17-22, 24-26 and 28-30 were rejected under 35 U.S.C. §102(a) as being anticipated by Cooper (*Int. J. Immunopathol. Pharmacol.* 16:289-292, 2003). This reference, published less than a year before the filing date of the present application, provides an overview of neuroimmune relations in autism. The section of this reference that is relevant to the pending claims may be found at pages 291-292. This paper provides no new information beyond what was already in the literature. The author simply provides commentary and refers to several papers by Aristo Vojdani, the sole inventor of the present application. The papers relating to the claimed subject matter to which the author refers are numbers 4, 11, 12 and 14. References 4 and 11 have been cited by the Examiner in the present Office Action. References 12 and 14 are stated to be "in press". Thus, as stated in paragraph 5 of the enclosed *In re Katz* Declaration, it is clear that Cooper is referring the inventor's own work, and the two publications mentioned are addressed herein. Thus, the claims cannot be anticipated by this reference.

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In view of the claim amendments ~~and comments~~ provided above, Applicant respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(a).

CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 29, 2006

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